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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CAPPS, KEVIN J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,428	MOO-YOUNG ET AL.	
	Examiner	Art Unit	
	Kevin J. Capps	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This Office Action is in response to the Remarks and Amendments filed on January 30, 2006. Applicant's amendment of claim 1 and cancellation of claims 2 and 17-22 in the Amendments filed on January 30, 2006, is acknowledged. Claims 1, 3-16, and 23 are pending and examined on the merits herein.

2. In view of Applicant's amendments and response, the following new non-final rejections are being made.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on April 15, 2004, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is being considered by the Examiner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735).

7. Bardin et al. teach, "A method for providing androgen hormone supplementation to a human male patient...comprising administering...7α-methyl-19-nortestosterone...wherein the testosterone derivative is administered...transdermally in an amount of from 5 to 10 μg/kg of body weight." (claim 4). Transdermal administration of from 5 to 10 μg/kg of body weight of 7α-methyl-19-nortestosterone in the method of Bardin et al. overlaps the range of 7α-methyl-19-nortestosterone delivered by the instantly claimed dosage form for a 70 kg male.

8. Bardin et al. do not teach the transdermal dosage form used in the method.

9. Reed et al. teach transdermal drug delivery systems for the delivery of active substances (claim 1; abstract). Reed et al. teach suitable dosage forms for transdermal delivery of the active agents, including ointments, creams, lotions, gels, sprays, and patches (p. 7, lines 6-20). Reed et al. teach suitable vehicles for transdermal delivery of active compounds which are well-known and have been described in various US

Patents (p. 7, lines 6-20). Reed et al. teach that 7α-methyl-19-nortestosterone is suitable for transdermal delivery in the well-known formulations.

10. It would have been obvious to the person of ordinary skill in the art at the time of invention to formulate 7α-methyl-19-nortestosterone at the doses taught by Bardin et al. in the transdermal delivery devices taught by Reed et al. to arrive at the instant invention.

11. The person of ordinary skill in the art would have been motivated to formulate 7α-methyl-19-nortestosterone at the doses taught by Bardin et al. in the transdermal delivery devices taught by Reed et al. to arrive at the instant invention because Bardin et al. teach that the herein-claimed dose of 7α-methyl-19-nortestosterone is effective for transdermal delivery, and Reed et al. suggests various transdermal delivery systems which can be used to transdermally deliver active compounds. The person of ordinary skill in the art would have expected success because Reed et al. teach that 7α-methyl-19-nortestosterone is suitable for incorporation into the well-known transdermal delivery systems.

12. Although Bardin et al. and Reed et al. do not disclose the flux of 7α-methyl-19-nortestosterone in the transdermal delivery systems, the flux is an inherent property of the transdermal delivery dosage form comprising 7α-methyl-19-nortestosterone which is rendered obvious by the teachings of Bardin et al. and Reed et al. See MPEP § 2112.01, paragraph I, which states, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or

obviousness has been established," (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)), and, "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, see MPEP § 2112.01, paragraph II, which states, "'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."

13. Bardin et al. and Reed et al. also do not disclose the herein-claimed preferred weight percentage of 7α-methyl-19-nortestosterone in the transdermal delivery system. Applicant's attention is directed to *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) which states, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05, "II. Optimization of Ranges". Formulations for the transdermal delivery of 7α-methyl-19-nortestosterone are suggested by Bardin et al. and Reed et al. Thus, optimization of the weight percent of 7α-methyl-19-nortestosterone in the well-known transdermal delivery systems is not considered inventive because it is a matter of routine experimentation for the ordinary skilled artisan.

14. The submission of the Declaration by Dr. Bardin averring that at the time of the Bardin et al. Patent application, no work had been done on transdermal delivery of 7α-methyl-19-nortestosterone, is acknowledged. However, as stated in the previous Office Action, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103". The Bardin et al. Patent is sufficient motivation for the person of ordinary skill in the art to look for references which teach known formulations for transdermal delivery of 7α-methyl-19-nortestosterone in the method of Bardin et al. Upon examining the Reed et al. document, the person of ordinary skill in the art would expect that 7α-methyl-19-nortestosterone could be formulated in the transdermal delivery systems taught by Reed et al. at the doses taught by Bardin et al. because Reed et al. teach that 7α-methyl-19-nortestosterone can be formulated as such.

15. Claims 1, 3-6, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834).

16. Jain et al. teach a patch device for transdermal delivery of androgen sex hormones with a 3-keto-4-en functional group, including methyl testosterone (claim 8; col. 4, line 49-col. 5, line 15). 7α-methyl-19-nortestosterone is an androgen sex hormones with a 3-keto-4-en functional group. Jain et al. exemplify a transdermal patch comprising 2 weight percent of testosterone (Example 7).

17. Jain et al. do not teach 7α-methyl-19-nortestosterone as a preferred sex hormone for use in the patches. Jain et al. do not teach the herein-claimed dose of 7α-methyl-19-nortestosterone in the patch.

18. As discussed above, Bardin et al. teach transdermal delivery of 7α-methyl-19-nortestosterone at a dose which overlaps the herein-claimed dose.

19. It would have been obvious to the person of ordinary skill in the art at the time of invention to formulate 7α-methyl-19-nortestosterone in the patch of Jain et al. at the dose taught by Bardin et al. to arrive at the instantly claimed invention.

20. The person of ordinary skill in the art would have been motivated to formulate 7α-methyl-19-nortestosterone in the patch of Jain et al. at the dose taught by Bardin et al. with a reasonable expectation of success because Jain et al. generally teach formulation of methyltestosterones and androgen sex hormones in patches for transdermal delivery, and Bardin et al. teach that the herein-claimed doses are effective for transdermal delivery of 7α-methyl-19-nortestosterone in a method of providing sex hormone supplementation.

21. As discussed above, although the references do not discuss the flux of 7α-methyl-19-nortestosterone in the transdermal patches, this is an inherent property of the transdermal patches which are rendered obvious by the combined teachings of the cited references. As is also stated above, optimization of the doses and weight percent of 7α-methyl-19-nortestosterone in the patches is not considered inventive because it is within the purview of the ordinary skilled artisan through routine experimentation.

22. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735) as applied to claims 1 and 3-16 above, and further in view of Moo-Young et al. (US 5,733,565).

23. Bardin et al. in view of Reed et al. suggest the transdermal delivery systems comprising 7α-methyl-19-nortestosterone, as discussed above.

24. Bardin et al. and Reed et al. do not suggest the use of the acetate salt of 7α-methyl-19-nortestosterone.

25. Moo-Young et al. teach the acetate salt of 7α-methyl-19-nortestosterone as preferred for use in an implantable system for subcutaneous or local administration of the androgen (claim 9; col. 3, lines 21-22).

26. It would have been obvious to the person of ordinary skill in the art at the time of invention to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Bardin et al. in view of Reed et al.

27. The person of ordinary skill in the art would have been motivated to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Bardin et al. in view of Reed et al. because Moo-Young et al. teach that this particular salt is preferred for implants which subcutaneously deliver the androgen. The person of ordinary skill in the art would have expected success because both transdermal and subcutaneous delivery systems target the active agent to the skin. Thus, 7α-methyl-19-nortestosterone acetate would be expected to be effective in the transdermal systems suggested by Bardin et al. in view of Reed et al.

28. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834) as applied to claims 1, 2-6, and 13-16 above, and further in view of Moo-Young et al. (US 5,733,565).

29. Jain et al. in view of Bardin et al. suggest transdermal delivery dosage forms comprising 7α-methyl-19-nortestosterone, as discussed above.

30. Moo-Young et al. teach the use of 7α-methyl-19-nortestosterone acetate as a preferred salt for local delivery of the androgen in the skin.

31. It would have been obvious to the person of ordinary skill in the art at the time of invention to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Jain et al. in view of Bardin et al.

32. The person of ordinary skill in the art would have been motivated to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Jain et al. in view of Bardin et al. because Moo-Young et al. teach that this particular salt is preferred for implants which subcutaneously deliver the androgen. The person of ordinary skill in the art would have expected success because both transdermal and subcutaneous delivery systems target the active agent to the skin. Thus, 7α-methyl-19-nortestosterone acetate would be expected to be effective in the transdermal systems suggested by Jain et al. in view of Bardin et al.

Double Patenting

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 1, 3-16, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-23 of copending Application No. 10/741,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to transdermal delivery systems comprising 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate and methods of using said systems.

35. '207 teaches transdermal delivery systems comprising an androgen, including 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate, and methods of using said systems. The dose of the sex hormones in the systems of '207 is within the

scope of the instantly claimed doses. Although '207 does not teach the flux of the transdermal dosage forms, this is an inherent property of the formulations.

36. '207 does not teach the preferred weight percent of the sex hormones in the formulation, this is a matter of routine experimentation for the ordinary skilled artisan. '207 also encompasses androgens other than 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate.

37. It would have been obvious to the person of ordinary skill in the art to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate as the preferred androgen and to optimize the weight of the formulation based on routine experimentation to arrive at the instantly claimed inventions.

38. The person of ordinary skill in the art would have been motivated to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate because '207 teaches formulations comprising androgens. Thus, the person of ordinary skill in the art would expect 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate to be effective because it is an androgen. The person of ordinary skill in the art would have been further motivated to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate as the androgen because they are exemplified as preferred androgens in claim 14.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

39. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin J. Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER